IN THE ARIZONA SUPREME COURT

STATE OF ARIZONA,) No. CR-87-0135-AP
Appellee,) Pima County Superior Court) Nos. CR14065 and CR15397
v. FRANK JARVIS ATWOOD,) Ninth Circuit No. 14–99002
Appellant.) U.S. District Court No. CV–98–116–) TUC–JCC
)) (Capital Case)

APPELLANT'S OPPOSITION TO MOTION TO MODIFY, AND CROSS-MOTION TO VACATE, BRIEFING SCHEDULE

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ARGUMENT

Because of purported "highly extraordinary circumstances," the State now seeks to modify the Court's execution warrant briefing schedule entered on May 21, 2021 (the "Scheduling Order"). *Motion to Modify Briefing Schedule* at 1 (the "Motion" or "Mtn.," 6/22/21) (quoting Scheduling Order). The State makes these claims a month after entry of the Scheduling Order—and eight weeks after Mr. Atwood's motion dedicated to correcting the State's misconceptions on the very issue it has brought to the Court. The State now alleges extraordinary circumstances "in the form of new information recently acquired from [ADCRR] bearing on the compounded pentobarbital's beyond-use date." *Id.* at 1-2. But the pharmaceutical information the State relies on as "new" is not at all new.

Whatever the genesis of the State's current position,¹ the Attorney General now concedes what Mr. Atwood had already submitted to this Court, *viz.*, that Arizona cannot carry out what is known as "extemporaneous compounding" of pentobarbital (*infra*) in order to conduct an execution under any lawful schedule²—including, of

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¹ The alleged change in the State's compounding pharmacist's opinion (Mtn. at 2) could be a product of the May 14, 2021, expert Declaration of James A. Ruble, R.Ph., Pharm.D., J.D., attached as an exhibit in support of *Appellant's Reply to Response to Motion for Assignment for Evidentiary Development* (5/14/21). Prof. Ruble chiefly addresses "the medical and scientific legitimacy of Arizona's purported '90-day shelf life' for compounded pentobarbital," and proceeds to explain, *inter alia*, pharmaceutical compounding, high-risk sterile compounding, beyond-use dating, quality assurance of APIs, and quantitative analyses. Attached hereto as Ex. A is Prof. Ruble's May 14, 2021, declaration.

² See Appellant's Motion for Assignment for Evidentiary Development (4/28/21) (the "Evidentiary Mtn.," 4/28/21), highlighting the preliminary requirement to test the viability of the active pharmaceutical ingredient ("API"). *Id.* at 4.

course, the very Scheduling Order that the Court has entered after receiving the parties' extensive briefing and the State's unfounded claims in its initial attempt to radically compress the warrant issuance process.

In the Scheduling Order, this Court resisted the Attorney General's initial unfounded insistence on an immediate turnaround for Mr. Atwood's response memorandum to a motion for a warrant and, instead, ordered the ordinary ten business days to responded provided by ARCAP 6(a)(2). Retaining that response period is necessary to uphold the State's obligation pursuant to federal litigation to supply Mr. Atwood with quantitative analysis of the pentobarbital compounded for the planned execution by ten *calendar* days after its motion for an execution warrant. That obligation is a central condition in the 2017 settlement of the federal suit following the botched execution of Mr. Joseph Wood in 2014. The Court should once again decline the State's expedited briefing request, which would undermine the testing and disclosure obligation integral to the resolution of the condemned prisoner's cruel and unusual punishment and procedural due process claims from the federal suit.

For the reasons presented herein, Mr. Atwood opposes the Motion and, due to the State's concession that it cannot lawfully conduct an execution under the current Scheduling Order (Mtn. at 3), and acknowledgment of the prudence in putting off any execution warrant motion (*id.* at 4 n.2 ("State respectfully moves in the alternative for a temporary stay of the briefing schedule.")), simultaneously moves the Court to

vacate that order of May 21, 2021, to leave the State to return to this Court after the Department of Corrections' retained pharmacist has conducted the requisite steps for a lawful execution.

I. The State Aims to Extemporaneously Compound Pentobarbital but Cannot Under a Lawful Execution Schedule.

A. The State Fails to Acknowledge the Vital Distinction Between Extemporaneous and Engineered Compounding

At the center of the matter is a 45 days beyond-use date for compounded pentobarbital. Mr. Atwood previously emphasized this well-established, *best case* outer limit for pentobarbital,³ which is a high-risk compound sterile preparation ("CSP").⁴ The State only now accepts this outer limit after it previously ignored and dismissed the clearly established pharmaceutical science concerning CSPs.⁵

The beyond-use date of any compounded pharmaceutical that the State may intend to use under an execution protocol is crucial to the settlement stipulation of

 $^{^{3}}$ *Id.* at 3.

⁴ Appellant argued "that high-risk level compounded sterile preparations ("CSPs") . . . have a maximum beyond-use date of 45 days." *Id.* at 4 n.4.

⁵ The State did not concede the error in its reliance on a 90-day beyond-use date, stating that its prior representation was based on "good-faith reliance" on the advice of its pharmacist. Mtn. at 2. Yet long before the Motion was filed, Mr. Atwood disclosed an expert declaration and citations to relevant regulations unequivocally showing that a 90-day beyond-use date was unsupportable. Evidentiary Mtn. at 3-5; Reply to Response to Motion for Assignment for Evidentiary Development at 1-6 (5/14/2021). The State dismissed this clear guidance out of hand, but gave no contradictory evidence supporting its pat conclusion. Response to Motion for Assignment for Evidentiary Development at 2-3 (5/7/21). While undersigned do not suggest the State was purposefully misleading, it is difficult to characterize such a willful disregard of the facts as "good faith." Cf. Stewart v. Thornton, 116 Ariz. 107, 110 (1977) ("Bad faith is not just being careless. It is guilty knowledge or willful ignorance.") (emphasis supplied).

the parties to the federal civil litigation after Arizona's last execution in July 2014.⁶ It is precisely the State's fear of violating these settlement terms that has impelled it to file this Motion. Mtn. at 3. Under the *Wood* Settlement, the State, *inter alia*, is proscribed from using "in an execution any chemicals that have an expiration or beyond-use date that is before the date that an execution is to be carried out." Any showing in the federal court of the State's intention to proceed with an execution in breach of those or other settlement terms would precipitate injunctive measures.8

As Mr. Atwood previously pointed out,9 the United States Pharmacopeia and National Formulary ("USP") provides the state's "official compendium" and guidelines for pharmaceutical regulation. A.R.S. §32-1901(61). The constraints these standards place upon compounding pharmacists with respect to beyond-use dates and other matters are essential to understanding the distinction between "extemporaneous" and "engineered" compounding processes. ¹⁰ That distinction is decisive for gathering the State's lawful means to readying itself to resume executions.

⁶ Hedlund, et al. v. Ryan, No. 2:14-cv-01447-PHX-NVW, Docs. 186-187 (the "Wood Settlement," attached here as Ex. B). Mr. Atwood is a Condemned Prisoner Beneficiary to that settlement. Ex. B, Doc. 186 at 6.

⁷ Ex. B, Doc. 187 at 2-3.

⁸ *Id.* at 3-4.

⁹ Evidentiary Mtn. at 3.

¹⁰ See generally L.V. Allen, Extemporaneous prescription compounding, in THE SCIENCE AND PRACTICE OF PHARMACY (2 vols., 22nd ed.), L.V. Allen et al., eds (London, 2012); David B. Troy, Ch. 105: Extemporaneous Prescription Compounding, in REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACV (London, 2006); see also Ex. C, Declaration of James A. Ruble, R.Ph., Pharm.D., J.D, July 7, 2021, at 3 (describing "extemporaneous"), at 5-6 (describing "engineered" practices).

While the State provides no basis for the evidently newly discovered 45 days beyond-use date other than the averments of its unnamed pharmacist, 11 that figure is consistent with the USP governing standards for an extemporaneous, or "spur of the moment," compounding of pentobarbital. 12 The State now acknowledges this reality, belatedly, but has yet to demonstrate its pharmacist's capacity to perform the other responsibilities attendant to this function within the Department's execution protocol.¹³ However, such capacity to conduct extemporaneous compounding is beside the point currently in relation to the active pharmaceutical ingredient ("API") Arizona has apparently procured (at a cost of \$1.5 million), ¹⁴ in order to resume executions. As the State acknowledges in seeking modification of the Scheduling Order, even flawless extemporaneous compounding cannot overcome the time requirements demanded under the State's obligations from the Wood Settlement and Arizona's law for obtaining and conducting an execution warrant. The present Motion recognizes that a 45 days beyond-use date is not long enough under the minimum

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¹¹ See Mtn. at 2.

¹² USP, General Chapter 797, *Pharmaceutical Compounding – Sterile Preparations* (2018), at 5-6. Notably, the 45-day beyond-use date maximum applies to high-risk CSPs (as well as low- and medium-risk ones). *Id.* at line 32. (Cited in Evidentiary Mtn. at 4 n.4).

¹³ Ex. C, Ruble Dec. (7/7/21) at 3 (questioning, e.g., "the competence of the pharmacist to perform the myriad related elements in compounding, including freezing and keeping stably frozen the given high-risk CSP for the 45 days in order for that 45 days BUD to actually apply to it. Such a swing in opinion is erratic and suggests unreliability.")

¹⁴ Ed Pilkington, Revealed: Republican-led states secretly spending huge sums on execution drugs, THE GUARDIAN (Apr. 9, 2021), available at

https://www.theguardian.com/world/2021/apr/09/revealed-republican-led-states-secretly-spending-huge-sums-on-execution-drugs (last accessed July 7, 2021).

duration of Arizona's motion and warrant processes. However, the State fails to recognize the implications of its federal settlement for resuming lethal injection executions. These terms, in their legal context, dictate a more rigorous, engineered, compounding approach, which is consonant with the changes to the State's execution protocols brought on in the aftermath of the botched 2014 execution date. Infra at I(B).

In contrast to spur of the moment compounding, a competent compounding pharmacist would carry out an engineered compounding contemplating greater preparation and testing. Competent compounding pharmacists would carry out an engineered approach including stability and sterility testing of the given CSP. 15

At this moment, however, the State concedes the Department of Corrections' retained pharmacist has yet to commence such testing. Mtn. at 2. While the State has engaged "pharmaceutical consulting services" in relation to compounding, it is not clear what these services have concerned, although, as of February 24, 2021, the State appears to have incurred at least \$440,000.00 (four-hundred, forty thousand dollars), ¹⁶ in fees for them.

¹⁵ Ex. C, Ruble Dec. (7/7/21) at 3.

¹⁶ Jimmy Jenkins, Arizona Backtracks on Expiration Date for Death Penalty Drugs, KJZZ 91.5, Jun. 23, 2021, available at https://kjzz.org/content/1693810/arizona-backtracks-expiration-date-deathpenalty-drugs (last accessed July 7, 2021) (disclosing information KJZZ obtained via public records requests).

The State's averments purportedly animating the recent submissions to this

Court call into question the competence of the pharmaceutical services the

Department has engaged in relation to resuming executions. ¹⁷ Fortunately, the Federal Bureau of Prisons (the "BOP") provides a recent concrete example acknowledging the steps for testing to establish extended beyond-use dating in the resumption of lethal injection executions after a long (17-year) hiatus. In order to compound pentobarbital with sufficient stability and potency to perform as intended in an execution protocol, the BOP acknowledged that certain steps were unavoidable. Thus, before embarking on its recent string of 13 executions concluding on January 16, 2021, the BOP undertook such engineered compounding. ¹⁸

Pursuant to engineered compounding practices, the Department's retained pharmacy must first obtain API with a Certificate of Analysis attesting to its adequacy

¹⁷ *Supra* n.11.

¹⁸ Attached as Ex. D, is the Nov. 12, 2019 Declaration of Raul Campos, Associate Warden at the Federal Medical Center at Carswell, Texas, from *In the Matter of the Federal Bureau of Prisons' Execution Protocol Cases*, No. 1:19-mc-00145-TSC, Doc. 36-1. Assoc. Warden Campos explains the BOP's steps in resuming executions.

On October 26, 2018, the BOP received a gram of pentobarbital sodium powder, the API, as a sample from a bulk manufacturer. Its Certificate of Analysis included an entry of "Fail" under the Related Compounds, Results field. The BOP then received new API accompanied by passing quality assurance testing attestations on February 21, 2019. The BOP's retained compounding pharmacy converted the API into an injectable solution, pursuant to its formulation. An initial round of testing in April 2019 was carried out, followed by a 365-day study of the stability of the solution, also commenced in April 2019.

A point of contention reflected by Assoc. Warden Campos concerned "stability testing purportedly show[ing] that the injectable solution demonstrated inadequate stability and potency at elevated temperature." Doc. 36-1 at 2-3. On July 14, 2020, approximately three months after the conclusion of this 365-day study started in April 2019, the Government executed Mr. Daniel Lewis, the first of 13 to be executed between that date and January 16, 2021.

on all qualitative measures.¹⁹ The pharmacist would prepare the API within its formulation for compounded injectable pentobarbital solution, and submit samples for extended stability and sterility studies to determine the exact beyond-use date for this particular batch.²⁰ These foregoing basic steps present the means for the State to prepare compounded injectable pentobarbital fit for its intended purpose under the Department's execution protocol and would likely produce such pentobarbital with a longer beyond-use date.²¹

These compounding pharmacy dictates were certainly evident in 2017, when the Attorney General resolved *Wood* and accepted its settlement obligations. *Infra*. Imposing pharmaceutical rigor upon the Department before it resumes lethal injection executions is a clear consequence from terribly botching Mr. Wood's execution. Yet the State persists in seeking to sidestep this sensible obligation it accepted, in part, for the sake of avoiding a reprise of the horrendous mishandling of its solemn responsibilities. The State's current, dramatic reappraisal of the beyond-use date of its lethal injection drug (Mtn. at 2), has only exacerbated the remaining concern over the capacity of the Department to carry out a lawful execution.

 $^{^{19}}$ Ex. C, Ruble Dec. (7/7/21) at 6.

²⁰ *Id*.

²¹ *Id*.

B. The Binding *Wood* Settlement and Arizona's Appellate Rules and Execution Statute Require the State to Engineer its Compounding Before Resuming Executions.

The State seeks a briefing schedule that would require Mr. Atwood's response to its inevitable motion for an execution warrant before the State would need to produce, pursuant to the *Wood* Settlement, perhaps the most critical information Mr. Atwood would need in opposing the motion: testing data concerning the adequacy of the specific batch of pentobarbital compounded for his lethal injection. The Wood Settlement consists of the litigants' Covenant Nos. 1 through 7 resolving plaintiffs' claims six (cruel and unusual punishment) and seven (procedural due process),²² which had survived the defendants' dismissal motion.²³ Covenant No. 5 marks substantial departures from the Department of Corrections' pre-Wood execution protocol and comprises a central part of Wood's resolution that permanently binds the State with respect to every current or future condemned prisoner. *Id.* at 5. Specifically, the State must "provide upon request, within ten calendar days after the State of Arizona seeks a warrant of execution, a quantitative analysis of any compounded or non-compounded chemical to be used in an execution that reveals, at a minimum, the identity and concentration of the compounded or non-compounded chemicals." Id. at 2.

²² Ex. B, Doc. 186

²³ Attached here as Ex. E, Doc. 117)

Before Mr. Wood's July 2014 execution date, the March 26, 2013, version of the Department [of Corrections] Order 710 contemplated a dramatically different approach to the Department's discretion, disclosure, and testing. Before the *Wood* Settlement, the Department operated under (i) a pharmaceutical testing requirement done on or within 30 days before an execution date—and thereby only *after* the entry of an execution warrant—and (ii) a requirement only 20 days before an execution date to notify the condemned of the specific drug protocol that the Department would use.²⁴

This dramatic alteration of prior Department practice emanated from the *Wood* plaintiffs' procedural due process claim (claim seven, *supra*), which, as the federal district court noted in denying its dismissal, "overlap[ped] with their Eighth Amendment claim, but it ultimately aim[ed] to vindicate the inmates' ability to protect their Eighth Amendment rights."²⁵ The federal district court further explained,

A case can be made for a procedural due process right to know ahead of time the critical aspects of the intended execution. The Eighth Amendment protects inmates from execution methods that pose a substantial risk of serious pain if another available method would significantly reduce the risk. For this protection to have effect, inmates must be able to challenge critical aspects of their own execution. The "right to be heard before being condemned to suffer grievous loss of any kind . . . is a principle basic to our society." ²⁶

²⁴ Attached here is Ex. F, DO 710 (Mar. 23, 2013), Attachment D at ¶¶ C.1-C.2.

²⁵ Ex. E, Doc. 117 at 14.

²⁶ Id. (quoting Joint Anti-Fascist Comm. v. McGrath, 341 U.S. 123, 168 (1951) (Frankfurter, J., concurring).

Clearly, the State's obligation to supply testing data shortly after any motion for an execution warrant, and *before* the appellate rules would require the condemned prisoner to respond, reflects the due process imperatives behind the settlement. At bottom, the Department's adherence to these important testing obligations must be understood in relation to the requirements of ARCAP 6(a)(2), which provide "10 days after service of the motion" for a response and "a reply memorandum within 5 days after service of a response," and A.R.S. §13-759(A), which calls for a 35-day period between entry of the warrant and the execution date.

Granting the present Motion's request for scheduling Mr. Atwood's response days *before* the State's date to provide testing of its compounding would vitiate that binding term of the *Wood* Settlement.²⁷ The current Scheduling Order, precipitated by the State's initial scheduling motion of April 6, 2021, rejects the compression of the briefing process that the State initially insisted was necessary for its resumption of executions, instead scheduling the State's warrant motion 34 days ahead of its August 24 conference date, specifying July 21 for that filing in order to allow for the needed

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The Scheduling Order rejected the State's first ploy to distort Arizona's appellate rules. But the State now returns seeking an even more extreme distortion, attempting to shrink the 16-day window it had originally proposed on April 6, 2021—and this Court providently rejected—down to a mere 11 days. The present Motion requests a revised scheduling that calls for the State's warrant motion on August 13, 2021, just 11 days from the Court's August 24 conference. Mtn. at 3. The State asks that Appellant respond four days later, on August 17. *Id.* Under this plan, the State would then reply a day later, on August 18, leaving the Court three business days—Thursday, August 19; Friday, August 20; and Monday, August 23—before its conference date earmarked to decide whether to issue an execution warrant. Conspicuously, on the same day as the Court's conference, the State would be due to submit to Appellant the results of its required testing pursuant to the *Wood* Settlement (*supra*).

three-weeks for briefing and a sufficient pre-conference period for the Court's review of the papers.²⁸

Further, this testing is not a formality; it is a hard-won material settlement term following the State's gross mishandling of its last execution. Testing possesses such importance because confidence in the use of any given prepared lethal injection pharmaceutical cannot exist without it. Before the 13 federal executions during the past calendar year, the sodium pentobarbital API procured by the Government's compounding pharmacy failed its testing.²⁹ In 2015, for another example, Georgia aborted an execution due to the emergence of impurities in its compounded pentobarbital that clouded the injectable liquid's composition.³⁰

II. Compounding Pharmacy's Clear Standards Are Neither New Information Nor Extraordinary Circumstances

Throughout the recent motion practice, Mr. Atwood repeatedly emphasized the specific pharmaceutical bases that now animate the State's second attempt to discard longstanding rules and circumvent its key testing obligations under the *Wood* Settlement. Boldly, the State seeks to pass off as newly emergent circumstances the very long-established pharmaceutical realities Mr. Atwood already explained and

²⁸ The Scheduling Order then calls for Appellant's response ten business days later, on August 4, and the State's reply, one week after that on August 11, leaving eight business days for the Court to review the filings before its conference date.

²⁹ Supra n. 18 (noting failed Certificate of Analysis in first API batch delivered to compounder).

³⁰ Rhonda Cook, *Two executions now on hold because of cloudy drugs*, ATLANTA JOURNAL CONSTITUTION, Sep. 24, 2016 (https://www.ajc.com/news/crime--law/two-executions-now-hold-because-cloudy-drugs/VFIRI8d60U6eR19xOLTjXJ/).

which the State had sought to discredit as presenting "no material factual dispute bearing on the State's motion to set a briefing schedule." *Response to Motion for Assignment for Evidentiary Development* at 2 (5/7/21). The Motion's circumstances simply are by no means new and any competent compounding pharmacist would have been very aware of these rudimentary elements of compounding for *any* level of CSP, be it low-, medium-, or, as in the case of pentobarbital, high-risk.³¹ *Id.* This purported impetus fails to justify the Motion and raises grave doubts about the capability of those handling the resumption of executions for the Department and its consulting services provider.

As Mr. Atwood has set forth, the State has a great deal to demonstrate before this Court can have any confidence that it is able to conduct a lawful execution under its new execution protocol. Plainly, the State's given reason for the present motion—that their compounding pharmacist failed to recognize that the beyond-use date was clearly established under prevailing guidelines and provides only 45 days, or half the 90-day period that the State originally relied upon—directly calls into question the fundamental competence of the retained compounding pharmacy to perform under Arizona's protocol.

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³¹ See generally Ex. A, Ruble Dec. (5/14/21) at 5-7; see also Ex. C, Ruble Dec. (7/7/21) at 3.

III. Conclusion

The State concedes that the current briefing schedule is untenable. Its proffered solution, however, is a modified schedule that would trample Mr. Atwood's rights and undermine the important obligations imposed by the *Wood* Settlement while offering nothing to give confidence in its ability to lawfully compound drugs for use in an execution. Accordingly, this Court should deny the present Motion, vacate the Scheduling Order, and instruct the State to seek a warrant when it is able to compound drugs and timely provide related testing information in a manner consistent with its legal obligations.

RESPECTFULLY SUBMITTED this 7th day of July, 2021.

/s/Natman Schaye

Natman Schaye Sam Kooistra

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